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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,688	05/17/2005	Carolyn Ann Foster	TX/4-32544A	4630

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,688	FOSTER ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/03/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 12/29/2008. Claim(s) 12-16 are pending and are examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 12-16 as being unpatentable over Fujita (US Patent No. 6,187,821 B1) in view of http://www.mult-sclerosis.org/opticneuritis.html (referred to as "ON website" heretofore) in further view of Hughes (US Patent No. 5,138,051) has been fully considered but is not persuasive.

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

First and foremost, Examiner would like to clarify Applicant's contention that the "ON website" is not prior art. Examiner draws Applicant's attention to page 3 of the pdf publication where the original date in which the publication was posted is made of record, specifically January 20, 2002. The date of January 21, 2008 cited by Applicant is the current date of the publication, however employing the "wayback machine" link, it is

noted that the publication was originally published in January 20, 2002 which is prior to Applicants effective filing date. Thus the ON website does qualify as a § 102/§ 103 reference.

Applicants argue that Fujita discloses methods of treating at least 180 diseases, including multiple sclerosis, comprising administering the compounds of formula I. Further it is argued that Fujita does not teach optic neuritis.

This argument is not persuasive. Although Fujita does teach several diseases, treating autoimmune disorders is taught (claim 16), specifically multiple sclerosis (claim 22). In reference to Fujita's deficiency on the teachings of optic neuritis, Examiner set forth for the record in the previous office action (mail date 6/25/08) the lack thereof.

Applicant further argues that one would not be motivated to combine the teaching of Fujita with that of Hughes. Because Fujita and Hughes teach compositions that are both employed for the same purpose, namely multiple sclerosis, one of ordinary skill in the art would be motivated to combine them. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Furthermore because, as taught by the ON website, optic neuritis is an inflammation with accompanying demyelination of the optic nerve and is one of the most frequently presenting symptoms of multiple sclerosis, one of ordinary skill in the art would expect, with a reasonable degree of success, that based on the teachings of

Fujita, the benzene compounds of formula I, taught to treat multiple sclerosis and a variety of eye diseases would also be effective in treating optic neuritis, a demyelinating eye condition.

The rejection is hereby maintained and is restated below for Applicant's convenience.

Information Disclosure Statement

The information disclosure statement filed 3/21/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Applicants may, in response to this and no later Office Action, submit the missing references. Such submissions will be considered to have been part of the respective Information Disclosure Statement filed on 3/21/2005, and the PTO-1449 will be updated accordingly. No fee for the submission of such references is required, nor should applicants file an additional form PTO-1449 with the missing references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujita (US Patent No. 6,187,821 B1) in view of http://www.mult-sclerosis.org/opticneuritis.html (referred to as "ON website" heretofore) in further view of Hughes (US Patent No. 5,138,051).

Fujita teaches a series of benzene compounds of formula I (tables 1- 24) which greatly overlap in scope to Applicant's compounds encompassed by formula I of claim 12. Specifically, Fujita teaches 2-amino-2-[2-(4-octylphenyl) ethyl]butane-1,4-diol (table 19, 1st entry, claim 9) and 2-amino-2-[2-(4-octylphenyl) propyl]butane-1,4-diol (table 18, 2nd entry).

Fujita teaches the benzene compounds as immunosuppressants for the treatment of various autoimmune diseases including multiple sclerosis (column 79, line 61- column 81, line 50; claims 16-22). The compounds can also be employed in the treatment of certain eye diseases including conjunctivitis, keratoconjunctivitis, keratitis, vernal conjunctivitis, uveitis associated with Behçet's disease, herpetic keratitis, conical cornea, dystorphia epithelialis corneae, keratoleukoma, ocular pemphigus, Mooren's ulcer, scleritis, Graves' ophthalmopathy, severe intraocular inflammation and the like (column 80, lines 43-50).

Furthermore, Fujita teaches the benzene compounds of formula I can be administered with other immunosuppressants (such as rapamycin), steroids, and nonsteroidal anti-inflammatory agent.

Fujita does not specifically teach the compounds as treating the eye disease optic neuritis. Fujita does not teach 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol or 2-amino-2-{2-[4-(1-oxo-5- phenylpentyl)phenyl]ethyl}propane-1,3-diol. Additionally, Fujita does not discuss the clinical effectiveness of rapamycin against a demyelinating disease.

The ON website teaches that optic neuritis is an inflammation with accompanying demyelination of the optic nerve and is one of the most frequently presenting symptoms of multiple sclerosis.

Hughes teaches that rapamycin is effective in the experimental allergic encephalitis model, a model for multiple sclerosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered the benzene compounds for the treatment of autoimmune disorders such as multiple sclerosis, a demyelinating disease, and other eye disorders as taught by Fujita and also have administered said compounds for the treatment of optic neuritis. The motivation, provided by the ON website, teaches that optic neuritis is an inflammation with accompanying demyelination of the optic nerve and is one of the most frequently presenting symptoms of multiple sclerosis. Thus because Fujita teaches that the benzene compounds are used to treat multiple sclerosis and an assorted variety of eye diseases, one would expect with a reasonable degree of success that said compounds would also be effective in treating optic neuritis, a demyelinating eye condition.

Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol to treat optic neuritis. Compounds that differ only by the presence of an extra methyl group are homologues which are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue. The homologue is expected to be preparable by the same method and to have the same properties. This expectation is then deemed the motivation for preparing homologues. Homologues are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39.

Conclusion

Claims 12-16 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617